

Applicant: Lucio Giambattista et al.

Application No: 10/824,304

Filed: April 14, 2004

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**Amendments to the Drawings:**

The attached sheet of drawings includes a change to Figure 7. This sheet, which includes only Figure 7, replaces the original sheet including Figure 7.

Attachment: Replacement Sheet

**REMARKS**

Reconsideration of the application as amended is respectfully requested.

Claims 24-26, 31-40, 45-47, and 50-55 are in the application. Claims 27-30, 41-44, 48-49, 56 and 57 have been cancelled.

For the record, paragraph [0025] has been amended to correct two typographical errors. Two instances of the phrase “pen needle 20” have been replaced with the phrase --safety shield assembly 23--. It is clear from the figures that the open end 26 and the external ribs 28 are formed on the safety shield assembly 23, not the pen needle 20. See, Figure 1. Moreover, paragraph [0028] of the specification states, “The external surface of the cap may also include ribs 28 to assist in gripping the cap during assembly of the safety shield assembly 23 on the pen injector 20.” It is respectfully submitted that the corrections to paragraph [0025] are in form only and do not include new subject matter.

In the Official Action, the Examiner objected to the drawings under 37 C.F.R. §1.83(a). Specifically, the Examiner asserted that “the indicating areas and visual indications must be shown or the feature(s) canceled from the claim(s).” In response, attached hereto is an annotated copy of Figure 7 in which reference number 53 has been added, which represents in indicating area. A formal drawing including this change can be submitted upon indication of allowance of the subject application. It is respectfully submitted that the drawings, as amended, are in accord with 37 C.F.R. §1.83(a).

The Examiner also objected to the specification as allegedly failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Examiner indicated that “a description of the claimed indicating areas and visual indications must be disclosed.” In response, paragraphs [0026] and [0032] have been amended to recite

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the indicating area and visual indicator. In view of the amendment, it is respectfully submitted that the specification is in accord with standard U.S. practice.

The Examiner rejected claims 25-35, 37-44, 46-49, 51-52, and 54-57 as allegedly failing to comply with the written description requirement under 35 U.S.C. §112, first paragraph. The Examiner asserted that “applicant fails to teach or disclose any reference to a visual indicator, indicating area, or additional claimed details of a visual indicator and indicating area in the specification and drawings.”

The Examiner’s assertions are respectfully traversed.

As indicated above, paragraphs [0026] and [0032] have been amended to affirmatively recite an indicating area and visual indicator. Figure 7 has not been amended and these features are clearly present therein, as well as in other figures. Accordingly, these features were present in the original application as filed. It is respectfully submitted that all the amendments made herein do not add new matter, and the claims are in compliance with 35 U.S.C. §112, first paragraph.

The Examiner rejected claims 24, 31, 36, 45, 50 and 53 under 35 U.S.C. §102(b) as being allegedly anticipated by Berthier (U.S. Patent No. 5,429,612).

Berthier is directed to a syringe with a slideable needle protecting device. The Examiner relied on the embodiment of Figure 1 of Berthier in formulating the rejection and referenced element 10 as being a “visual indicator”. Element 10 in Berthier is a “small diameter portion” of needle protector 8. (See, e.g., column 3, lines 27-32). With the Berthier device, the needle protector 8 starts and returns to the position shown in Figure 1. Once used, the needle protector 8 is locked so as not to be re-usable. (Column 4, lines 23-31). There is, however, no visual difference between the pre-use and post-use positions of the needle protector 8.

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Claims 24, 31, 36, 45, 50 and 53 are all the independent claims of the subject application. Each of the independent claims includes a “visual indicator” or “visual indication” to indicate that the device is in a locked or safe position. In contrast, the embodiment of Figure 1 of Berthier has no such indicator or indication. No distinction can be made in the pre-use and post-use positions of the Berthier device as relied upon by the Examiner. It is respectfully submitted that claims 24, 31, 36, 45, 50 and 53 are patentable over Berthier.

The Examiner rejected claims 25-30, 32-35, 37-44, 46-49 and 51-57 under 35 U.S.C. §103(a) as being unpatentable over Berthier in view of Lewandowski (U.S. Patent No. 5,674,203). The Examiner noted that Berthier fails to disclose a “lock or hub having an indicating area and at least one additional indicating area, the safety shield having a transparent area or an opening through which the indicating areas are visible, the indicating areas and additionally [sic] indicating areas providing difference [sic] visual indications, and the visual indication showing a colored surface or textured surface after the shield is irreversibly locked.” The Examiner relied on Lewandowski for allegedly overcoming these deficiencies.

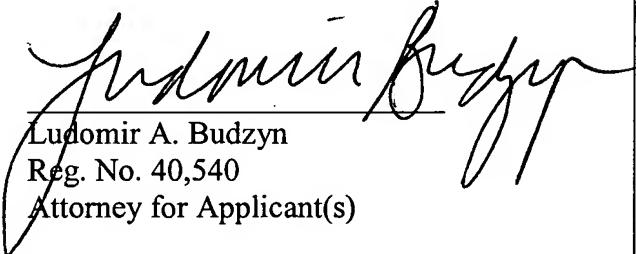
Lewandowski discloses a safety needle device which is activated upon extension of a sliding needle shield. (See, e.g., column 5, lines 16-19). The Lewandowski device only has two positions: pre-use and post-use. These are different positions. With the Berthier device, the pre-use and post-use positions are the same. Thus, with the hypothetical combination of Berthier and Lewandowski, the Lewandowski indicating area would not differentiate between pre- and post-usage. The indicating area would have the same alignment in both positions. As indicated above, the claims of the subject application require a visual indication of a locked or safe state. The hypothetical combination of Berthier and Lewandowski is incapable of providing such an indication.

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It is respectfully submitted that the claims of the subject application are allowable over Berthier and Lewandowski, each taken above or in combination.

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicant's attorney at the number listed below.

Respectfully submitted,

  
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